

APPLICATION FOR NEW COURSE

1. Submitted by the College of Public Health Date: March 10, 2008

Department/Division proposing course: Biostatistics

2. Proposed designation and Bulletin description of this course:

a. Prefix and Number EPI 715

b. Title* Research Methods in Epidemiology and Biostatistics

*If title is longer than 24 characters, write a sensible title (24 characters or less) for use on transcripts:

Research Methods

c. Courses must be described by at least one of the categories below. Include the number of actual contact hours per week for each category, as applicable.

- () CLINICAL () COLLOQUIUM () DISCUSSION () LABORATORY (3) LECTURE
 () INDEPEND. STUDY () PRACTICUM () RECITATION () RESEARCH () RESIDENCY
 () SEMINAR () STUDIO () OTHER – Please explain: _____

d. Please choose a grading system: Letter (A, B, C, etc.) Pass/Fail

e. Number of credit hours: 3

f. Is this course repeatable? YES NO If YES, maximum number of credit hours: _____

g. Course description:

This course builds a broad array of skills that are useful for the design and development of research protocols and funding applications for peer review, and for the analysis of resultant scientific data.

h. Prerequisite(s), if any:

BST 760 (Advanced Regression), EPI 714 (Epidemiologic Study Design), and BST 639 (Computing Tools)

i. Will this course be offered through Distance Learning? YES NO

If YES, please circle one of the methods below that reflects how the majority of the course content will be delivered:

- Internet/Web-based Interactive video Extended campus Kentucky Educational Television (KET/teleweb) Other

Please describe "Other": _____

3. Teaching method: N/A or Community-Based Experience Service Learning Component Both

4. To be cross-listed as: _____
 Prefix and Number Signature of chair of cross-listing department

5. Requested effective date (term/year): Spring / 2010

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6. Course to be offered (please check all that apply): Fall Spring Summer
7. Will the course be offered every year? YES NO
If NO, please explain: _____
8. Why is this course needed?
This course is a requirement in the proposed PhD in Epidemiology/Biostatistics.
-
9. a. By whom will the course be taught? Claudia Hopenhayn or Amit Chattopadhyay
- b. Are facilities for teaching the course now available? YES NO
If NO, what plans have been made for providing them?

10. What yearly enrollment may be reasonably anticipated?
5-10 students
11. a. Will this course serve students primarily within the department? Yes No
- b. Will it be of interest to a significant number of students outside the department? YES NO
If YES, please explain.
The course will be a requirement for the proposed Ph.D. in Epidemiology/Biostatistics, which spans two departments..
It may also be of interest to graduate students from other colleges and to the MPH and Dr.PH students in the College of Public Health.
12. Will the course serve as a University Studies Program course[†]? YES NO
If YES, under what Area? _____
[†]AS OF SPRING 2007, THERE IS A MORATORIUM ON APPROVAL OF NEW COURSES FOR USP.
13. Check the category most applicable to this course:
- traditional – offered in corresponding departments at universities elsewhere
 - relatively new – now being widely established
 - not yet to be found in many (or any) other universities
14. Is this course applicable to the requirements for at least one degree or certificate at UK? Yes No
15. Is this course part of a proposed new program? YES NO
If YES, please name: PhD in Epidemiology and Biostatistics
16. Will adding this course change the degree requirements for ANY program on campus? YES NO
If YES[†], list below the programs that will require this course:

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[†]In order to change the program(s), a program change form(s) must also be submitted.

17. The major teaching objectives of the proposed course, syllabus and/or reference list to be used are attached.
18. Check box if course is 400G or 500. If the course is 400G- or 500-level, you must include a syllabus showing differentiation for undergraduate and graduate students by (i) requiring additional assignments by the graduate students; and/or (ii) the establishment of different grading criteria in the course for graduate students. (See SR 3.1.4)
19. Within the department, who should be contacted for further information about the proposed new course?

Name: Richard Kryscio Phone: 257-4064 Email: kriscio@email.uky.edu

20. Signatures to report approvals:

4-1-08
DATE of Approval by Department Faculty

GUYNG. CALDWELL Guyng Caldwell
printed name Reported by Department Chair signature

6-26-08
DATE of Approval by College Faculty

Linda Alexander Linda Alexander
printed name Reported by College Dean signature

* DATE of Approval by Undergraduate Council

printed name Reported by Undergraduate Council Chair signature

12/22/08
* DATE of Approval by Graduate Council

Blair Jackson Blair Jackson
printed name Reported by Graduate Council Chair signature

8/19/08
* DATE of Approval by Health Care Colleges Council (HCCC)

Herli Anderson Herli Anderson
printed name Reported by Health Care Colleges Council Chair signature

* DATE of Approval by Senate Council

Reported by Office of the Senate Council

* DATE of Approval by University Senate

Reported by Office of the Senate Council

*If applicable, as provided by the University Senate Rules. (<http://www.uky.edu/USC/New/RulesandRegulationsMain.htm>)

EPI 715: Research Methods in Epidemiology and Biostatistics

Course Description: In this course students will develop broad skills that are useful for the design and development of research protocols and funding applications for peer review, and for the analysis of resultant scientific data. Topics include, but are not restricted to: methods of evaluating research proposals; mechanisms of funding; specifying human subjects considerations; developing a set of research questions; designing a study to address these questions; consideration of sampling, study population, data collection methods, data management and appropriate data analysis techniques; writing a research proposal for a study; developing an appropriate budget and budget justification; writing a human subjects proposal where appropriate; developing a realistic timeline for the study; writing critiques of proposals.

Course Structure: 3 credit hours (3 hours of lecture).

Prerequisites: BST 760 (Advanced Regression), EPI 714 (Epidemiologic Study Design), and BST 639 (Computing Tools) or equivalent.

Initial Offering: Spring 2010

Instructors: The course leader can be any faculty member in the Departments of Biostatistics or Epidemiology. This course will be taught by a team of two or more faculty from the graduate group in Epidemiology and Biostatistics.

Philosophical Statement: Students with doctoral training in biostatistics and epidemiology who pursue careers in academia, business, industry, or government must be able to develop, implement, and carry out to completion a research protocol designed to address scientific questions in the biosciences. This includes identifying a research project, generating statistically testable hypotheses, designing an appropriate study, data collection and management, and conducting and/or supervising an appropriate statistical analysis.

Objectives: On successful completion of the course, students will be able to

1. develop and write a statistically testable hypothesis from a biologic question and under various epidemiologic study designs
2. understand and utilize the theory and practice of designing experimental and observational studies in epidemiologic and biostatistics research to address biomedical hypotheses
3. understand the purposes of randomization and masking, and the selection of study participants to achieve comparability of study groups and to avoid selection bias
4. perform sample size and power calculations to achieve adequate statistical power
5. Evaluate data integrity and sampling methods for data collection to avoid recall and interviewer biases, design and analytic approaches to avoid

confounding bias, and to evaluate data for confounding and effect modification

6. Apply theory and concepts of biostatistics and epidemiology to analysis and interpretation of common types of data generated in epidemiologic and biostatistics research
7. Evaluate, recommend, and interpret results from appropriate modeling approaches and statistical methods for complex epidemiologic data
8. Communicate study design and details, results of a data analysis, and interpretation of findings using a format suitable for scientific publication or presentation at a professional conference
9. identify and discuss strengths and limitations of research studies
10. understand how to write and review research proposals

References: Lecture notes will be provided by the instructors.

Detailed Outline:

I. Research Plan 1: Overview

Sources of funding

Methods of review

Selection of topics and hypothesis

Statement of objectives and specific aims, background and significance

Summarize literature and results from preliminary studies

II. Research Plan 2: Epidemiologic study design

Overview of epidemiologic study designs: the randomized trial, and observational case-control and prospective designs

Strengths and limitations of study design, potential for bias.

Measurement: assessment of exposure and disease in cohort and case-control studies

Comparability: confounding and causal inference.

III. Research Plan 3: Sampling and selection

Sampling and selection of subjects

Human subjects

Achieving comparability in cohort and case-control studies – matching, stratification, adjustment

Choice of index groups (exposed or case) in cohort and case-control studies

Choice of comparison groups (unexposed or control) in cohort and case-control studies

Follow-up in randomized clinical trials and cohort studies

Increasing participation, reducing attrition

Methods of data collection and management

Biologic sampling

Strengths and limitations of data, collection methods, potential for bias

IV. Research Plan 4: Data analysis

Sample size and power directed to specific aims in clinical trials, cohort, and case-controls studies

Issues in the analysis of epidemiologic data from cohort and case-control studies: confounding and interaction

Data description: data integrity, procedures for examining data, detecting and considering outliers, recoding, missing data, data presentation and graphics

Univariate analysis and initial data exploration

Bivariate and multivariate analysis

Selecting a statistical modeling approach for the hypothesis: distributions of variables, appropriate transformations

Variable selection and modeling steps: stepwise vs. thought-wise. Inclusion of confounders and effect modifiers

Deriving causal inferences

Describing study limitations

V. Research Plan 5: Budget and budget justification

Personnel - investigators, staff

Equipment – freezer, centrifuge, computer, supplies, assays, documents, copying, phones, faxes, stationery

Travel – subject, staff, investigator

Subcontracts, consulting

VI. Research Plan 6: Reviewing research proposals

Strengths and limitations of design, subject recruitment and retention, methods of data collection and analysis, experience and capability of investigators, adequacy of budget and timeline, scoring system and funding

VII. Research Plan 7: The end product

Communicating of methods and results

Writing proposals

Reviewing proposals

Assessment: Grades will be based on problem sets (40%), a written project proposal and presentation (40%), and a critical review of another student's project proposal (20%).

Grading Scale:

Grade	%
A	90-100
B	80-89
C	70-79
E	60-69

Nikou, Roshan

From: Pauly, Jim
Sent: Tuesday, December 02, 2008 9:17 AM
To: Nikou, Roshan; Spear, Brett
Subject: FW: EPI715

Here is a response from Dr. Kryscio for EPI 715. I recommend approval pending the suggested changes in the syllabus, as outline below.

----- Forwarded Message

From: "Pauly, Jim" <jpaul@uky.edu>
Date: Mon, 01 Dec 2008 18:20:59 -0500
To: "Kryscio, Richard" <kryscio@email.uky.edu>
Subject: Re: EPI715

Thanks Dick - I will copy this email to the rest of the Council and move for approval on Thursday. I appreciate the speedy reply. Thanks again, j

On 12/1/08 5:38 PM, "Kryscio, Richard" <kryscio@email.uky.edu> wrote:

- > Jim:
- >
- > I consulted the two listed instructors: Dr David Mannino and Dr. Adam
- > Branscum for their thoughts on your questions.
- > Below are their responses. I am copying our Administrative Assistant
- > since she will make sure these change are made to the document.
- >
- > I am a member of the Graduate Council and responsible for
- > reviewing the EPI715 application for a new course. In general the
- > application is very straightforward. But I do have a couple of small
- > questions that I hope you can help me out on.
- >
- > 1. The title "Research Methods" seems generic for the transcript.
- > Wouldn't EPI&BIOSTATS or something like that be more descriptive?
- >
- > Entitle the course: Research Methods in Epidemiology and Biostatistics.
- > Running title: Research Methods EPI&BST
- >
- > 2. You may think about adding "or consent of instructor" to the
- > requirements sections, in case a student enters the Epidemiology
- > program,

- > already holding an advanced degree in Biostats.
- >
- > We agree: please add Consent of Instructor
- >
- > 3. Are there any course materials, besides lecture handouts?
- >
- > Two possible texts follow:
- > (i) Modern Epidemiology 3rd Ed. Authors: K.J. Rothman, S. Greenland,
- > and T.L. Lash. Publisher: Lippincott, Williams & Wilkins, 2008
- > (ii) Epidemiology: Study Design and Data Analysis. Author: Woodward.
- > Chapman & Hall/CRC Press, 1999.
- >
- > 4. There is not much information of the problem sets and how they will
- > be
- > used to calculate 40% of the students grade.
- >
- > We envision 4 class projects each worth 10% of the final grade. Two will
- > focus on epidemiology but will have statistical content and two will
- > focus on statistics but will have epidemiology content.
- >
- > 5. You may want to consider adding some additional information about
- > course
- > attendance policies and other things like a plagiarism policy.
- >
- > Course attendance is expected with unexcused absences docked in
- > accordance with the instructor's syllabus but no less than 2% debit from
- > the final course average for each class missed. The Departments of
- > Biostatistics and epidemiology, the College of Public Health, and the
- > University of Kentucky place a premium on academic honesty. Please
- > refer to the University of Kentucky Student Rights and Responsibilities
- > document (www.uky.edu/StudentAffairs/Code/part2.html).
- >
- > Let me know if these responses meet your expectations.
- >
- > Dick Kryscio

----- End of Forwarded Message